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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 111130706-1686-01]

Impact of Implementing the Chemical Weapons Convention (CWC) on Commercial Activities Involving “Schedule 1” Chemicals through Calendar Year 2011; Impact of Adding Salts of CWC “Schedule 1” Chemicals to “Schedule 1;” Impact of Declaring Production of “Schedule 1” Chemicals as Intermediates

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact that implementation of the Chemical Weapons Convention (CWC), through the Chemical Weapons Convention Implementation Act (CWCIA), and the Chemical Weapons Convention Regulations (CWCR), has had on commercial activities involving “Schedule 1” chemicals during calendar year 2011. Additionally, BIS seeks public comments on whether the addition of salts of

certain CWC “Schedule 1” chemicals (e.g., saxitoxin or nitrogen mustards) to the list of “Schedule 1” chemicals in the CWC Annex on Chemicals would impact any commercial activities. Finally, BIS is seeking public comments on whether any commercial chemical production activities in the U.S. could possibly involve the production of a “Schedule 1” chemical as an intermediate in the synthesis of other chemicals. In this regard, note that the CWC, CWCIA, and CWCR have the potential to impact commercial activities, not only when the “Schedule 1” chemicals are end products, but whenever “Schedule 1” chemicals (e.g. nitrogen mustards) are produced as intermediates in the synthesis of other chemicals.

DATES: Comments must be received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: wfisher@bis.doc.gov. Include the phrase “Schedule 1 Notice of Inquiry” in the subject line;
- Fax: (202) 482-3355 (Attn: Willard Fisher);
- Mail or Hand Delivery/Courier: Willard Fisher, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th Street & Pennsylvania Avenue, N.W., Room 2705, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for “Schedule 1” chemicals, contact Douglas Brown, Treaty

Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-1001. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482-2440.

SUPPLEMENTARY INFORMATION:

Background

The purpose of this notice of inquiry is threefold: (1) to collect information to assist BIS in its preparation of the annual certification to the Congress that is required under Condition 9 of Senate Resolution 75, April 24, 1997, in which the Senate gave its advice and consent to the ratification of the Chemical Weapons Convention; (2) to collect information that would assist BIS to evaluate whether salts of certain “Schedule 1” chemicals should be added to the list of “Schedule 1” chemicals; and (3) to collect information that would indicate to BIS whether any “Schedule 1” chemicals, or salts thereof, are produced as intermediates in the commercial production of some other chemical.

Request for comments concerning the impact of implementing the Chemical Weapons Convention (CWC) on commercial activities involving “Schedule 1” chemicals through Calendar Year 2011

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC) (the Convention), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 9, titled “Protection of Advanced Biotechnology,” calls for the President to certify to Congress on an annual basis that “the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1.” On July 8, 2004, President Bush, by Executive Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). The CWC imposes certain obligations on countries that have ratified the Convention (i.e., States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons, and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties for the purpose of achieving the object and purpose of the Convention and the implementation of its provisions. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not

engaged in activities prohibited under the CWC.

“Schedule 1” chemicals consist of those toxic chemicals and precursors set forth in the CWC “Annex on Chemicals” and in Supplement No. 1 to part 712 of the Chemical Weapons Convention Regulations (CWCRC) (15 CFR parts 710-722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC restricts the production of “Schedule 1” chemicals for protective purposes to two facilities per State Party. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103-21 defined the term “protective purposes” to mean “used for determining the adequacy of defense equipment and measures.” Consistent with this definition, U.S. implementation, as authorized via Presidential Decision Directive (PDD) 70, December 17, 1999, assigned the responsibility to operate these two facilities to the Department of Defense (DOD), thereby precluding commercial production of “Schedule 1” chemicals for protective purposes in the United States. The Department of Defense maintains strict controls on “Schedule 1” chemicals produced at its facilities in order to ensure the accountability and proper use of such chemicals, consistent with the object and purpose of the Convention. These actions did not establish any limitations on “Schedule 1” chemical activities that are not prohibited by the CWC. However, the CWC stipulates a one metric ton limit for “Schedule 1” chemicals in a State Party.

The provisions of the CWC that affect commercial activities involving “Schedule 1” chemicals

are implemented in the CWCR (see 15 CFR 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of “Schedule 1” chemicals to research, medical, or pharmaceutical purposes. Other industrial uses are prohibited. The CWCR also contain other requirements and prohibitions that apply to “Schedule 1” chemicals and/or “Schedule 1” facilities. Specifically, the CWCR:

- (1) Prohibit the import of “Schedule 1” chemicals from States not Party to the Convention (15 CFR 712.2(b));
- (2) Require annual declarations by certain facilities engaged in the production of “Schedule 1” chemicals in excess of 100 grams aggregate per calendar year (i.e., declared “Schedule 1” facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));
- (3) Require government approval of “declared Schedule 1” facilities (15 CFR 712.5(f));
- (4) Provide that “declared Schedule 1” facilities are subject to initial and routine inspection by the Organization for the Prohibition of Chemical Weapons (15 CFR 712.5(e) and 716.1(b)(1));
- (5) Require 200 days advance notification of establishment of new “Schedule 1” production facilities producing greater than 100 grams aggregate of “Schedule 1” chemicals per calendar year (15 CFR 712.4);
- (6) Require advance notification and annual reporting of all imports and exports of “Schedule 1” chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of “Schedule 1” chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, “Schedule 1” chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the Chemical Weapons Convention, through the Chemical Weapons Convention Implementation Act and the Chemical Weapons Convention Regulations, has had on commercial activities involving “Schedule 1” chemicals during calendar year 2011. To allow BIS to properly evaluate the significance of any harm to commercial activities involving “Schedule 1” chemicals, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Request for comments concerning the impact of adding salts of certain CWC “Schedule 1” chemicals to the list of “Schedule 1” chemicals in the CWC Annex on Chemicals

The OPCW has recently been considering whether to add salts of certain “Schedule 1” chemicals, specifically of saxitoxin and nitrogen mustards, to the list of “Schedule 1” chemicals in the CWC Annex on Chemicals. This would mean that the salts of these “Schedule 1” chemicals would likely be identified as “Schedule 1” chemicals, themselves. As a result, they too would become subject to any impact that implementation of the CWC, through the CWCIA

and the CWCR, has on commercial activities involving “Schedule 1” chemicals.

BIS seeks comments as to whether salts of any “Schedule 1” chemical, which are not currently listed as “Schedule 1” chemicals in the CWC Annex on Chemicals, are produced (as an end product or in a captive use situation), consumed, transferred, or stored in the United States. Note that, if the CWC were to add any of these salts to the list of “Schedule 1” chemicals in the CWC Annex on Chemicals, this could impact commercial activities in the event that these new “Schedule 1” chemicals were produced as intermediates in the synthesis of other chemicals. For example, such production or captive use by a facility, following a decision by the OPCW to add any of these salts to the list of “Schedule 1” chemicals in the CWC Annex on Chemicals, could subject that facility to the CWC requirements for destruction of “chemical weapons production facilities.”

Request for comments on whether any “Schedule 1” chemicals, or salts thereof, are produced as intermediates in the commercial production of some other chemical

As defined in 15 CFR 710.1, production of a “Schedule 1” chemical means formation through chemical synthesis as well as processing to extract and isolate “Schedule 1” chemicals. On November 10, 2005, the Organization for the Prohibition of Chemical Weapons (OPCW) decided, “that the production of a “Schedule 1” chemical is understood, for declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste

products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur” (C-10/DEC.12). At the time of this decision, there were no known examples of so-called captive use of “Schedule 1” chemicals. This is no longer the case. Based on new information provided by Denmark to the Executive Council of the OPCW, the United States is aware that a commercial pharmaceutical facility in Denmark produced a “Schedule 1” chemical (a nitrogen mustard), as an intermediate in the production of another chemical, which, arguably, would cause the facility to meet the definition of a Chemical Weapons Production Facility. While it appears unlikely that the pharmaceutical facility will be determined to be a Chemical Weapons Production Facility, Denmark has ordered the facility to halt future production of the pharmaceutical product and sought resolution through the OPCW Executive Council.

In view of this development, BIS is seeking public comments as to whether any similar situations of so-called captive use of a “Schedule 1” chemical may exist in the United States.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice. The Department requires that all comments be submitted in written form.

The Department encourages interested persons who wish to comment to do so at the earliest possible time. The period for submission of comments will close on [INSERT DATE 30 DAYS

AFTER DATE OF PUBLICATION]. The Department will consider all comments received before the close of the comment period. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the persons submitting the comments and will not consider them. All comments submitted in response to this notice will be a matter of public record and will be available for public inspection and copying.

The Office of Administration, Bureau of Industry and Security, U.S. Department of Commerce, displays public comments on the BIS Freedom of Information Act (FOIA) web site at <http://www.bis.doc.gov/foia>. This office does not maintain a separate public inspection facility. If you have technical difficulties accessing this web site, please call BIS's Office of Administration, at (202) 482-1093, for assistance.

DATED: December 5, 2011

Kevin J. Wolf

Assistant Secretary

for Export Administration

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